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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,598	06/30/2006	Beth C. Mullin	UTR-108XC1	5764

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EXAMINER	
IBRAHIM, MEDINA AHMED	
ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,598	MULLIN ET AL.	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-54,56,61-64 and 76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-54,56,61-64 and 76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/24/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 10/24/08 in reply to the Office action of 07/24/08 has been entered. Claims 52-54, 56, 61-65 are amended. Claims 52-56, 61-65 and 76 are pending and are examined. The sequence listings of 10/24/08 have been entered.

All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment. This Office action contains New grounds of rejection not necessitated by Applicant's amendment, therefore, is made non-final. Any inconvenience this may have caused Applicant is regretted.

Claim Rejections - 35 USC § 103

Claims 52-54, 56 and 61-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guerinot et al (US 5,846,821 A) in view of Pawlowski et al (MPMI (1997), vol.10 (5), pp. 656-664; Applicant's IDS) and Terry et al (US 6,576,816).

The claims are drawn to a transformed plant comprising an isolated polynucleotide encoding a polypeptide comprising SEQ ID NO: 1 or 4 ; a method of phytoremediation of sites contaminated with metals comprising identifying the site and cultivating said transformed plant under conditions that allow the accumulation of metals from said contaminated site and harvesting the transgenic plant to remove the metal contaminants from the site.

Guerinot et al teach a method of transforming a plant with an isolated polynucleotide encoding a glycine-histidine rich polypeptide to produce transformed plants capable of metal accumulation and suggests that the use of the transgenic plants in environmental pollution remediation. The cited reference also suggests that a phytoremediation method for removing heavy metals from soils contaminated with one or more heavy metals including mercury, cobalt, lead, arsenic, cadmium, zinc and copper (see columns 20-22, 29-30, 44 and Example 5).

Guerinot et al do not teach a polynucleotide encoding a polypeptide comprising SEQ ID NO: 1 or 4 and identification of metal contaminated site for phytoremediation of the site.

Pawlowski et al teach an isolated cDNA encoding a glycine and histidine rich AgNt84 protein having 100% identity to Applicant's SEQ ID NO: 1 which also comprises Applicant's SEQ ID NO: 3 and 4. Pawlowski et al also teach that the AgNt84 polypeptide contains a signal peptide having similarity with signal peptide from the nodule 24, the nodule specific protein from soybean. The cited reference teaches an E.coli host cell expressing the AgNt84 polypeptide encoded by the AgNt84 cDNA as fusion protein with maltose binding protein. Pawlowski et al suggest that because the polypeptide encoded by AgNt84 cDNA has the ability to bind to nickel resin it may function as a metal binding protein (see the whole document).

Terry et al teach a method of phytoremediation of sites contaminated with metals comprising identifying the site and cultivating said transformed plant under conditions that allow the accumulation of metals from said contaminated site and harvesting the

transgenic plant to remove the metal contaminants from the site, whereby the metal content of the site is reduced.

Therefore, it would have been obvious to one of ordinary skill in the art to use the method of transforming plants with an isolated polynucleotide sequence encoding glycine-histidine rich polypeptide to produce a transformed plant having heavy metal accumulating ability as taught by Guerinot et al and to modify that method by incorporating any other known glycine-histidine rich polynucleotide like the AgNt84 cDNA taught by Pawlowski et al, to produce transformed plants expressing AgNt84 as a metal binding protein as suggested by Pawlowski et al and use said plants for phytoremediation of heavy metal contaminated sites by first identifying the site; growing the transformed plants expressing the AgNt84 metal binding protein in said contaminated site such that the plants accumulate the metals from the site, and then harvesting the plants to remove the metals from the site with a reasonable expectation of success as taught by Terry et al. One would have been motivated to use the AgNt84 encoding polynucleotide in a transgenic plant given that the AgNt84 polypeptide functions as a metal binding protein as suggested by Pawlowski et al, and given that transgenic plants expressing other glycine-histidine polypeptide are capable of metal accumulation and phytoremediation as suggested by Guerinot et al. Therefore, the invention as a whole was prima facie obvious.

Claims 52-54, 56, 61-64 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guerinot et al (US 5,846,821 A) in view of Pawlowski et al (MPMI

(1997), vol.10 (5), pp. 656-664; Applicant's IDS) and Terry (US 6, 576, 816) as applied to claims 52-54, 56 and 61-64 above, and further in view of Sharma et al (US 5,594,115 A).

The teaching of Guerinot et al in view of Pawlowski et al and Terry are discussed above.

Guerinot et al in view of Pawlowski et al and Terry do not explicitly teach targeting a heterologous polypeptide with the AgNt84 protein a fusion protein to the cell wall of a plant cell.

Sharma et al teach recombinant fusion proteins which comprise a metal chelating peptide which have at least six alternating histidine residues. At the paragraph bridging columns 2 and 3, Sharma cites US 5, 569,794 that teaches recombinant DNA encoding fusion protein containing metal chelating peptides, including those containing histidine, attached to a desired polypeptide via a linker peptide. Sharma et al also teach that the fusion protein is produced by host cells transformed with the genetic information encoding the fusion protein. The host cells may secrete the fusion protein into the culture media or store it in the cells whereby the cells must be collected and disrupted in order to extract the product (see the whole document).

It would have been obvious to one of ordinary skill in the art at the time this application was filed to use the method of producing recombinant fusion protein with a metal chelating protein as taught by Sharma et al and to modify that method by incorporating any other metal chelating histidine rich proteins like the AgNt84 protein the SEQ ID NO:1 or its signal peptide as a fusion in a plant cell with a reasonable

expectation of success as taught by Sharma et al. The targeting of the protein into the cell wall of the plant is an inherent property of SEQ ID NO: 1 or its signal peptide. One would have been motivated to use the AgNt84 encoding polynucleotide in a transgenic plant cell given that the AgNt84 polypeptide functions as a metal binding protein as suggested by Pawlowski et al. Therefore, the invention as whole was a prima facie obvious.

Claim Rejections - 35 USC § 112

Claims 55 and 65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transformed plant comprising an isolated polynucleotide encoding SEQ ID NO: 1, does not reasonably provide enablement for transformed plant comprising a polynucleotide encoding a polypeptide consisting of SEQ ID NO: 4 or a method for phytoremediation metal contaminated sites by growing said plant in said contaminated site. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a transformed plant comprising an isolated polynucleotide sequence encoding a polypeptide consisting of SEQ ID NO: 4; a method for phytoremediation or bioremediation metal contaminated sites by growing said plant in said contaminated site. The specification provides guidance for a method of transforming a plant with a vector comprising an isolated polynucleotide encoding SEQ ID NO: 1 and a transgenic plant comprising said polynucleotide.

The specification, however, does not provide guidance for polynucleotides encoding a polypeptide other than SEQ ID NO: 1 that contains SEQ ID NO: 4. No guidance have been provided for a transformed plant comprising a polynucleotide encoding a polypeptide consisting of SEQ ID NO: 4, said transformed plant which can be used for phytoremediation of heavy metals contaminated sites. Applicant has not disclosed a single transformed plant having a phytoremediation property as result of expressing a polynucleotide encoding a polypeptide consisting of SEQ ID NO: 4. It is unpredictable that expression of a polynucleotide encoding a polypeptide consisting of a metal binding protein only will have any use. Neither the prior art nor Applicant's specification shows that a metal binding domain alone would be capable of binding heavy metal without the presence of other domains of the metal binding protein. Therefore, a transgenic expressing the metal binding domain of SEQ ID NO: 4 only is not expected to accumulate heavy metals, absent evidence to the contrary.

Genentech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997): The CAFC stated, "(P)atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable....While every aspect of generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention....[w]hen there is no disclosure of any specific starting material or conditions under which a process can be carried out, undue experimentation is required..... It is the specification, not the knowledge of one skilled in the art, that must

supply the novel aspects of an invention in order to constitute adequate enablement". Id. In this case, as in *Genentech*, the specification does not provide the "reasonable detail .....to enable members of the public to understand and carry out the invention" as broadly claimed.

Therefore, for all the reasons discussed above and in the last Office action, the claimed invention is not enabled throughout the broad scope.

Remarks

Claims 55 and 65 are free of the prior art.

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571)272-0797. The examiner can normally be reached on M-TH 8:00 am to 5:30 PM, and every other Friday from 8:00 AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAI
1/21/2009

/Medina A Ibrahim/
Primary Examiner, Art Unit 1638